

What is claimed.

1. A test element for determining the level of phenylalanine in a biological fluid comprising a layer onto which a sample of the biological fluid is applied and a reagent layer containing a material that is interactive with phenylalanine or a precursor of a reaction product of phenylalanine.
2. The test element of claim 1, wherein the reagent layer comprises an enzyme which converts phenylalanine to phenylpyruvate.
3. The test element of claim 2, wherein the reagent layer comprises phenylalanine dehydrogenase.
4. The test element of claim 1, wherein the reagent layer comprises buffered enzymatic colorimetric reagents wherein a reaction signals the presence/absence of phenylalanine.
5. The test element of claim 1, wherein the reagent layer comprises a buffer, a dye/mediator and enzyme/cofactor.
6. The test element of claim 1, wherein the reagent layer comprises a hydrophilic polymer.
7. The test element of claim 5, wherein the hydrophilic polymer is gelatin or agarose.
8. The test element of claim 4, wherein the colorimetric reagent is thionine, Rose Bengal, Methylene Blue, Azure C or a tetrazolium salt.
9. The test element of claim 5, wherein the mediator is 1-methoxy phenazine methosulfate.
10. The test element of claim 1, further comprising a support layer.
11. A medical device adapted for the monitoring of blood levels of phenylalanine utilizing colorimetric analysis, comprising a unit containing testing elements according to claim 1, or insertion means for receiving the test elements according to claim 1 having a test biological sample thereon and a means on said device for displaying a test result for a level of phenylalanine in the biological sample.
12. The device of claim 11, further comprising a memory means for storing previous biological sample results and means for displaying the stored biological sample result.

13. The device of claim 12, possibly comprising a means to allow phenylalanine determinations to be downloaded to physicians offices.
14. A device used in the monitoring of phenylalanine levels wherein the device is non-invasive utilizing, for example, interstitial fluids.
15. A method of determining the presence or absence of phenylalanine in a biological sample comprising applying the biological sample to a test strip according to claim 1 allowing the biological sample to react with the reagent layer and colorimetrically determining a level of phenylalanine in the biological sample.
16. The device of claim 11, wherein the device is a table-top plug-in device.
17. The device of claim 11, wherein the device is battery operated.
18. The device of claim 11, wherein the device is fuel-cell powered.